

4/9/99

K990363

**Summary of Safety and Effectiveness Information**

Premarket Notification, Section 510(k)

SAMYANG

CORPORATION

DECEMBER 1998

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

**1. Trade Name:*****BioMesh® Biodegradable GTR Barrier***

Common

Name(s): GTR Barrier

Classification

Name(s): Unclassified device

**2. Establishment Name & Registration Number:**

Name: SAMYANG CORPORATION

Number: Pending

**3. Classification:**

Device Class: II

Classification Panel: Dental

Product Code(s): LYC

**4. Equivalent Predicate Device:**

SAMYANG CORPORATION believes that ***BioMesh® Biodegradable GTR Barrier*** is substantially equivalent to Resolut Regenerative Material as characterized in K932866, K962624 and K973594.

1. Gore Resolut Regenerative Material, K932866, K962624 & K973594

Comparison of ***BioMesh® Biodegradable GTR Barrier*** brand GTR barrier to the predicate device(s) identified above based on available labeling, promotional materials, comparison testing, demonstrates the substantial equivalence of ***BioMesh® Biodegradable GTR Barrier***.

**5. General Device Description:**

***BioMesh® Biodegradable GTR Barrier*** is provided as a single membrane type, but in a variety of precut shapes and sizes. **Shapes and sizes.** As noted on the graphic representation at the left, five different shapes are offered. The ***BioMesh® Biodegradable GTR Barrier*** is shape optimized to provide a ready made pattern well suited to the selected operative site needing a minimum of surgeon modification. If desired, the surgeon can trim any of the available shapes to fit unique or unusual circumstances. The ***BioMesh® Biodegradable GTR Barrier*** is made from polyglycolic acid with a coating of polylactic acid + polylactic glycolic acid copolymer. The membrane is constructed with interconnective pores with an embossed surface.

**6. Applicant Name & Address:**

SAMYANG CORPORATION

263 Yeonji-dong, Chongno-gu

Seoul 110-725, Korea

**7. Company Contact:**

Mr. Dong-Kee Yoo  
**SAMYANG CORPORATION**  
263 Yeonji-dong, Chongno-gu  
Seoul 110-725, Korea  
Tel. 011.82.2.740.7296  
Fax 011.82.2.743.6626

**8. Submission Correspondent:**

Mr. David W. Schlerf  
Buckman Company, Inc.  
200 Gregory Lane, Suite C-100  
Pleasant Hill, CA 94523-3389  
925.356.2640 - 925.356.2654 - fax

**9. Performance Standards:**

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include U.S.P., ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

**10. Storage, Packaging & Sterilization Information:**

**Packaging.** Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Once opened, the product should never be resterilized or reused. **Storage.** Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. Rotate stock and observe shelf life dates. Discard when outdated or damaged. When used, the product must be placed into use following accepted surgical sterile technique. **Sterilization.** *BioMesh® Biodegradable GTR Barrier* is supplied "STERILE" and is terminally EtO sterilized in accordance with accepted standards.

**11. Summary Comparison Table:**

FEATURE	<i>BioMesh</i>	<i>Resolut</i>	SE?
Indications for Use:	Two or three wall vertical defects, Class II furcations, Circumferential defects, Recession type defects, Dehiscence defects associated with dental implants	SAME	YES
Material:	polyglycolic acid with a coating of polylactic acid + polylactic glycolic acid copolymer	Equivalent	YES
Structure:	microporous membrane made of biodegradable polyglycolide, polylactide and d,l-lactide/glycolide copolymer. The membrane is made up of interconnective pores with an embossed surface.	Non-woven membrane yes, no interconnecting pores, no embossing	Equivalent
Tissue Integration:	Test result score 115	Test result score 110	YES
Biocompatibility:	Good	Good	YES
Toxicity:	Good	Good	YES
Stability:	5 Years	5 Years	YES
Clinical Data:	Good	Good	YES
Manufacturer:	SAMYANG	GORE	YES
Product Code:	LYC	SAME	YES
K - Number:	Pending	K932866, K962624 & K973594	YES



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 9 1999

Samyang Corporation  
C/O Mr. David W. Schlerf  
Buckman Company, Incorporated  
200 Gregory Lane, Suite C-100  
Pleasant Hill, California 94523-3389

Re: K990363  
Trade Name: BioMesh® Biodegradable GTR Barrier  
Regulatory Class: II  
Product Code: LYC  
Dated: December 28, 1998  
Received: February 5, 1999

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

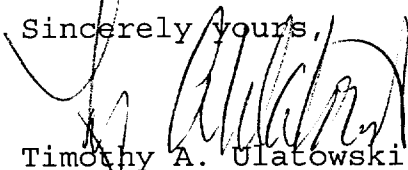
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Schlerf

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number : K990363

Device Name(s): **BioMesh® Biodegradable GTR Barrier**

**Intended Use(s) of the Device:**

**BioMesh® Biodegradable GTR Barrier** is intended for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures.


**Indications for Use:**

**BioMesh® Biodegradable GTR Barrier** is indicated for use in the treatment of the following specific conditions:

1. Two or three wall vertical defects.
2. Class II furcations.
3. Circumferential defects.
4. Recession type defects.
5. Dehiscence defects associated with dental implants

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K990363

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional format 1-2-96)